Liza M. Walsh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217
lwalsh@connellfoley.com

Charles Weiss
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, NY 10019
Telephone: 212-513-3551
Facsimile: 212-385-9010
charles.weiss@hklaw.com

*Attorneys for Defendants,*
*Actavis Inc., Actavis Laboratories, FL, Inc.,*
*Actavis Pharma, Inc., Watson Laboratories,*
*Inc., and Anda, Inc.*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| SUPERNUS PHARMACEUTICALS, INC.,<br><br>Plaintiff,<br><br>v.<br><br>ACTAVIS INC., ACTAVIS LABORATORIES, FL, INC., ACTAVIS PHARMA, INC., WATSON LABORATORIES, INC., and ANDA, INC.,<br><br>Defendants. | Civil Action No. 15-cv-02499(RMB/JS)<br><br>*Electronically Filed* |

**ANSWER OF ALL DEFENDANTS, AND**
**COUNTERCLAIM OF DEFENDANT ACTAVIS LABORATORIES, FL, INC.**

Defendants Actavis Inc., ("Actavis"), Actavis Laboratories, FL, Inc. ("AF"), Actavis Pharma, Inc. (“Actavis Pharma” ), Watson Laboratories, Inc. (“Watson Laboratories”), and Anda, Inc. (“Anda”) (collectively "Defendants"), by way of Answer to the Complaint, allege and say:

## NATURE OF THE ACTION

1. To the extent that Paragraph 1 of the Complaint states conclusions of law, Defendants state that no response is required. To the extent that a response is required, Defendants admit that Plaintiff purports to state claims that arise under the patent laws of the United States, and that a copy of United States Patent No. 8,821,930 (“the ’930 patent”) was attached to the Complaint as Exhibit A.

## THE PARTIES

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint.

3. Admitted that Actavis is a corporation organized under the laws of Nevada with a place of business at 400 Interspace Parkway, Parsippany, NJ 07054. Otherwise denied.

4. Admitted as to the first two sentences, with the exception of the identification of the principal place of business, otherwise denied.

5. Admitted.

6. Admitted.

7. Admitted as to the second and third sentences, and that Actavis Pharma is a Delaware corporation with an office at the stated address. Otherwise denied.

8. Admitted that Actavis Pharma conducts marketing, selling and distributing of pharmaceutical products throughout the United States, including throughout the State of New

Jersey. Admitted that Actavis Pharma is registered as a manufacturer and wholesale drug distributor in the State of New Jersey. Otherwise denied.

9. Admitted that Watson Laboratories is a Nevada corporation with an office at the stated address. Otherwise denied.

10. Denied.

11. Denied as pleaded. Admitted that Actavis subsidiaries sell pharmaceutical products throughout the United States, including New Jersey.

12. Admitted that Anda is a corporation organized and existing under the laws of Florida with a place of business at 2915 Weston Road, Weston, FL 33331. Otherwise denied.

13. Admitted that Anda distributes pharmaceutical products to pharmacies and physicians. Admitted that Anda is registered as a manufacturer and wholesale drug distributor in the State of New Jersey. Otherwise denied.

**JURISDICTION AND VENUE**

14. To the extent that Paragraph 14 of the Complaint states conclusions of law, Defendants state that no response is required. To the extent that a response is required, Defendants admit that Plaintiff purports to state claims that arise under the patent laws of the United States, and admit that the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) for the present case. Otherwise denied.

15. To the extent that Paragraph 15 of the Complaint states conclusions of law or makes allegations against other defendants, Actavis states that no response is required. To the extent that a response is required, Actavis states that it does not contest personal jurisdiction in New Jersey for purposes of this case.

16. To the extent that Paragraph 16 of the Complaint states conclusions of law or makes allegations against other defendants, Actavis Pharma states that no response is required. To the extent that a response is required, Actavis Pharma states that it does not contest personal jurisdiction in New Jersey for purposes of this case.

17. To the extent that Paragraph 17 of the Complaint states conclusions of law or makes allegations against other defendants, Watson Laboratories states that no response is required. To the extent that a response is required, Watson Laboratories states that it does not contest personal jurisdiction in New Jersey for purposes of this case.

18. To the extent that Paragraph 18 of the Complaint states conclusions of law or makes allegations against other defendants, AF states that no response is required. To the extent that a response is required, AF states that it does not contest personal jurisdiction in New Jersey for purposes of this case.

19. To the extent that Paragraph 19 of the Complaint states conclusions of law or makes allegations against other defendants, Anda states that no response is required. To the extent that a response is required, Anda states that it does not contest personal jurisdiction in New Jersey for purposes of this case.

20. Denied.

21. To the extent that Paragraph 21 of the Complaint states conclusions of law, Defendants state that no response is required. To the extent that a response is required, Defendants state that they will not contest venue for purposes of this case.

**FACTS AS TO ALL COUNTS**

22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of the Complaint.

23. Admitted.

24. Defendants admit that the '930 patent is entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof," and that the cover page of the '930 patent recites an issue date of September 2, 2014. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 24 of the Complaint. Otherwise denied.

25. Denied as pleaded, but admitted that the '930 patent is listed in FDA's electronic Orange Book for Oxtellar XR.

26. Denied.

27. To the extent that Paragraph 27 of the Complaint states conclusions of law, Defendants state that no response is required. To the extent that a response is required, Defendants state that the pertinent statutes speak for themselves. Otherwise denied.

28. Denied as pleaded, but admitted that AF sent the cited letter.

29. Admitted.

30. To the extent that Paragraph 30 of the Complaint states conclusions of law, Defendants state that no response is required. To the extent that a response is required, Defendants state that the document speaks for itself. Otherwise denied.

**FIRST COUNT**

31. In response to Paragraph 31 of the First Count, Defendants repeat their responses to Paragraphs 1 through 30 of the Complaint as if set forth at length herein.

32. In response to Paragraph 32 of the First Count, denied as pleaded, but admitted as to AF only. Otherwise denied.

33. In response to Paragraph 33 of the First Count, denied as pleaded, but admitted that AF seeks FDA approval of the proposed product that is the subject of ANDA No. 205444 before the expiration of the '930 Patent.

34. In response to Paragraph 34 of the First Count, denied.

35. In response to Paragraph 35 of the First Count, denied.

36. In response to Paragraph 36 of the First Count, denied.

37. In response to Paragraph 37 of the First Count, denied.

38. In response to Paragraph 38 of the First Count, denied.

**DEFENSES**

39. The Complaint fails to state a claim upon which relief may be granted.

40. The manufacture, use, offer for sale, sale, and/or importation of that certain proposed product that is the subject of ANDA No. 205444 would not infringe any valid claim of the '930 Patent.

41. The claims of the '930 Patent insofar as they may relate to that certain proposed product that is the subject of ANDA No. 205444 are invalid for failure to comply with one or more sections of Title 35, United States Code, including, but not limited to, sections 101, 102, 103, and 112.

42. Defendants reserve the right to assert additional defenses in the event that discovery or other analyses indicates that additional defenses are appropriate.

**COUNTERCLAIMS**

Counterclaimant Actavis Laboratories, FL, Inc. ("AF") asserts the following counterclaims against Supernus Pharmaceuticals, Inc. ("Counterclaim Defendant") that United States Patent No. 8,821,930 (the "'930 patent") is not infringed by the proposed product that is

the subject of ANDA No. 205444, and/or is invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

**THE PARTIES**

43. Defendant/Counterclaimant Actavis Laboratories, FL. Inc. ("AF") is a company organized and existing under the laws of Florida and with a place of business at 2945 W. Corporate Lakes Blvd., Weston FL Florida.

44. On information and belief, and based on Plaintiff's allegations, Counterclaim Defendant/Plaintiff Supernus Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

**NATURE OF THE ACTION**

45. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. AF seeks declarations that the '930 patent is not infringed by the proposed products that are the subject of AF's (f/k/a Watson Laboratories, Florida-Inc.) Abbreviated New Drug Application ("ANDA") No: 205444, and/or is invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

**JURISDICTION AND VENUE**

46. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between AF and Counter Claim Defendant/Plaintiff, arising under the patent laws of the United States, 35 U.S.C. § 1 et seq. This Court has original

jurisdiction over the subject matter of these claims under at least 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

47. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff based on, *inter alia*, Counterclaim Defendant/Plaintiff's filing of this lawsuit in this jurisdiction.

48. Venue is proper in this judicial district.

**BACKGROUND**

49. The '930 patent, on its face, is entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof," and lists its date of issue as September 4, 2014.

50. On information and belief, and based on Counterclaim Defendant's/Plaintiff's allegations, the '930 patent is owned by Supernus Pharmaceuticals, Inc.

51. On information and belief, and based on Counterclaim Defendant's/Plaintiff's allegations, Supernus Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 202810, which was approved by the FDA for the manufacture and sale of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, which Counterclaim Defendant/Plaintiff markets under the name Oxtellar XR.

52. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 202810 on October 19, 2012.

53. AF submitted ANDA No. 205444 to the FDA requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, before the stated expiration of the '930 patent. AF made a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the '930 patent would be

infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the proposed product that is the subject of ANDA No. 205444 (the "ANDA Product").

54. On April 7, 2015, Plaintiff filed their Complaint alleging infringement by AF, Actavis Inc., ("Actavis"), Actavis Pharma, Inc. ("Actavis Pharma" ), Watson Laboratories, Inc. ("Watson Laboratories"), and Anda, Inc. ("Anda") of the '930 patent.

**COUNT I**
**(Declaration of Invalidity of the '930 Patent)**

55. AF incorporates by reference Paragraphs 43 through 54 of its Counterclaims as if fully set forth herein.

56. The claims of the '930 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

57. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '930 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

58. AF is entitled to a judicial declaration that the '930 patent is invalid.

**COUNT II**
**(Declaration of Noninfringement of the '930 Patent)**

59. AF incorporates by reference Paragraphs 43 through 58 of its Counterclaims as if fully set forth herein.

60. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '930 patent.

61. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '930 patent under the doctrine of equivalents.

62. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the ANDA Product of the '930 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

63. AF is entitled to a judicial declaration that the '930 patent is not infringed.

**PRAYER FOR RELIEF**

**WHEREFORE**, Defendants AF, Actavis, Actavis Pharma, Watson Laboratories, and Anda, demand judgment again Counterclaim Defendant/Plaintiff:

A. Dismissing the Complaint with prejudice;

B. Declaring that the manufacture, use, offer for sale, sale, and/or importation of that certain proposed product that is the subject of ANDA No. 205444 does not infringe any valid claim of the '930 Patent;

C. Declaring that the claims of the '930 Patent, insofar as they may relate to that certain proposed product that is the subject of ANDA No. 205444 are invalid;

D. Finding that this case is exceptional under 35 U.S.C. § 285;

F. Enjoining Plaintiff, its officers, agents, employees, representatives, counsel and all persons in active concert or participation with Plaintiff, directly or indirectly, from threatening or charging infringement of, or instituting or maintaining any action for infringement of the '930 Patent on account of the manufacture, use, offer for sale, sale, and/or importation of that certain proposed product that is the subject of ANDA No. 205444;

G. Awarding attorneys' fees, expenses, and costs of suit; and

H. Awarding such other and further relief as may be appropriate.

Dated: April 30, 2015

By: *s/Liza M. Walsh*

Liza M. Walsh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217
lwalsh@connellfoley.com

Charles Weiss
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, NY 10019
Telephone: 212-513-3551
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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or any pending arbitration or administrative proceeding, but it is related to the subject matter of the following actions:

*Supernus Pharmaceuticals, Inc. v. Actavis Inc., et al.,* Civil Action No. 13-4740; and

*Supernus Pharmaceuticals, Inc. v. Actavis Inc., et al.,* Civil Action No. 14-1981.

The foregoing cases involve the same parties and Oxtellar XR® products marketed by Supernus Pharmaceuticals, Inc. The above cases have all been assigned to Hon. Renée M. Bumb, U.S.D.J. U.S.D.J.

April 30, 2015

By: *s/Liza M. Walsh*

Liza M. Walsh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217
lwalsh@connellfoley.com

Charles Weiss
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, NY 10019
Telephone: 212-513-3551
Facsimile: 212-385-9010
charles.weiss@hklaw.com

*Attorneys for Defendants, Actavis Inc., Actavis Laboratories, FL, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and Anda, Inc.*

**CERTIFICATION PURSUANT TO L. CIV. R. 201.1**

Pursuant to Local Civil Rule 201.1, Defendants, through their attorneys, certify that the above captioned matter is not subject to compulsory arbitration.

Dated: April 30, 2015

By: *s/Liza M. Walsh*

Liza M. Walsh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217
lwalsh@connellfoley.com

Charles Weiss
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, NY 10019
Telephone: 212-513-3551
Facsimile: 212-385-9010
charles.weiss@hklaw.com

*Attorneys for Defendants, Actavis Inc., Actavis Laboratories, FL, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and Anda, Inc.*